UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,905	07/28/2003	Gregory F. Brooks	17310CIP1CON1 (BOT)	7440

7590 06/20/2005

STEPHEN DONOVAN
ALLEGAN, INC.
T2-7H
2525 Dupont Drive
Irvine, CA 92612

EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,905	BROOKS ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) *21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,20 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on February 22, 2005 is acknowledged. Claims 19, 20 22-24 and newly added claim 25 are pending and under consideration. Claims 1-18 and 21 have been canceled and withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections Withdrawn

In view of Applicant's response the objection to the specification [illegible] for failure to provide antecedent basis (page 3 paragraph 4) is withdrawn.

Rejections Withdrawn

In view of Applicant's response the rejection over claims 19, 20, 22 and 23 (page 7, paragraph 6) is withdrawn.

In view of Applicant's response the rejections over claims 19, 20 and 22-24 under 35 U.S.C. 102 (b) and (e) (page 10-13) are withdrawn.

Objections Maintained

The objection to the specification under 37 CFR 1.58, MPEP 608.01 as having no page numbers is maintained for the reasons set forth on page 2, paragraph 4. An example of the specification is enclosed following this office action.

Rejections Maintained

The rejection of claim 23 under 35 U.S.C. 101 (double patenting) is maintained for the reasons set forth in the prior office action on page 6 paragraph 5. Applicant failed to either cancel or amended the conflicting claim so that it is no longer coextensive in scope. Submitting a terminal disclaimer does not overcome the rejection. In addition there has been no side-by-side comparison made to show that there is a difference between botulinum toxin and botulinum neurotoxin.

The rejection of claims 19, 20 and 22 under 35 U.S.C 112, first paragraph for failing to comply with the written description requirement is maintained for the reasons set forth in the prior office action page 9, paragraph 7. Applicant has not specifically identified where in the instant specification by page and line number -- the written support for this concept can be found.

The rejection of claims 19, 20, 22-24 and newly added 25 under 35 U.S.C. 103 is being maintained for the reasons set forth in the prior office action page 19, paragraph 9.

The rejection was on the ground that Vigil et al. discloses a device for injecting into a wall of a blood vessel. Vigil et al teaches a composition for use in a cardiovascular procedure (see figures). Figures 9-11 depict an inflatable balloon with multiple dispensing ports (little cups) within. The figure would meet the limitation of imbedded therein. If the toxin were in the dispensing ports the toxin would clearly be embedded therein.

Vigil et al teaches a composition for use in a cardiovascular procedure (see figures) comprising a stent (see abstract) with a toxin attached or embedded therein (column 3, lines 33-46), wherein the composition comprises a device with a multi-lumen catheter in which a toxin containing fluid resides for the injection of a blood vessel to treat stenosis. Vigil et al teaches administration of a toxin directly to a blood vessel (column 1, lines 23-30) of a patient, wherein the composition is administered during or after a cardiovascular procedure comprising a composition comprising a tube or balloon (column 4, lines 16-24) with a toxin attached or imbedded in dispensers therein (column 11, lines 47-54; column 3, lines 33-46) and the administering is accomplished through injection of a toxin containing fluid into the vessel. The injection device comprises an expandable multi-lumen catheter that administers the toxin containing fluid or slow release composition directly into a blood vessel. However, Vigil et al teaches suitable toxins such as pseudomonas exotoxin or Ricin A toxin (column 3, line 44). Vigil et al differs because they do not teach the limitation of a botulinum toxin.

Schramm et al has priority back to November 4, 1992. Application number 08/781,745 (page 3, lines 8-15) also teaches that pseudomonas toxins and botulinum toxins are both ADP-ribosylation toxins. ADP-ribosylation toxins are common in bacterial infections. These toxins include but are not limited to pseudomonas enterotoxin and botulinum toxin (column 3, lines 4-9).

Rappuoli et al (1997) teaches that when you combine botulinum neurotoxin type C strains with D strains they will produce the Clostridium botulinum C2 toxins and the botulinum C3 ADP-ribosyltransferase (page 108, 2nd ¶). Rappuoli also teaches the C2 toxin to be an ADP-ribosyltransferase (page 66, 2nd column).

It would have been *prima facia* obvious to a person having ordinary skill in the art at the time the invention was made to modify the composition of Vigil et al that comprises a expandable stent and a toxin to substitute the botulinum toxin of Rappuoli et al because Schramm et al teach both pseudomonas toxin and botulinum toxin function as ADP-ribosylating toxins, and substitution of one functional equivalent for another is routine in the art.

Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the prior art

(i.e., the composition of the prior art does not posses: a stent with botulinum toxin attached). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that a) Vigil et al disclose a device for injecting fluid into a blood vessel wall, b) Vigil et al disclose that the anti-proliferative agents are agents that kill rapidly dividing cells, c) Schramm et al disclose compounds that inhibit nucleoside hydrolase and transferase enzyme activity of parasites, d) Rappuoli et al disclose general information regarding C2, e) Schramm et al does not suggest a therapeutic use of any toxin and f) none of the above references disclose, teach, or even suggest the elements of the present claims.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). It is the examiner's position that the claims are drawn to a composition comprising a stent with a botulinum toxin attached or embedded wherein the botulinum toxin elutes from the stent. Moreover, the claims are drawn to a botulinum toxin, which the instant specification defines as an anaerobic, gram-positive bacterium clostridium botulinum, which produces a potent polypeptide neurotoxin. Again, there has been no side-by-side comparison made to show that there is a difference between botulinum toxin and botulinum neurotoxin. Lastly, applicant is arguing issues to which the claims are not drawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LJT

L. R. F. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600